

REMARKS

I. Non-Statutory Obviousness-Type Double Patenting

The Examiner has raised a non-statutory obviousness-type double patenting rejection against Claims 1, 3, and 7 of the present application as unpatentable in view Claims 1, 2, and 5 of commonly owned U.S. Pat. No. 7,091,337 ("the '337 patent").

The Examiner notes that this rejection may be overcome by submission of a terminal disclaimer. Without addressing the merits of the rejection, Applicants submit a terminal disclaimer with the appropriate fee herewith, in order to render this rejection moot. Entry of the terminal disclaimer and removal of the obviousness-type double patenting rejection are therefore respectfully requested.

II. 35 U.S.C. §102(b)

The Examiner has rejected Claims 11 and 13 under 35 U.S.C. §102(b) as anticipated by Cho et al., Korean Pub. No. 10-2000-0036332 (Reg. No. 10-0369518). According to the Examiner,

"Cho et al. teach preparation of low molecular weight heparin by exposing an aqueous solution of high molecular weight heparin using electron beam. This is seen to meet the limitations of instant claims 11 and 13." (See, Office Action, page 4.)

Applicants respectfully assert that it is axiomatic in patent law that for a reference to be anticipating, it must describe each and every limitation of the invention as claimed. The Cho et al. reference fails to teach the identical process as claimed by Applicants, and therefore the Cho et al. reference cannot anticipate the process for the depolymerization of glycosaminoglycans as disclosed and claimed in the present application. The present invention is directed to a process for the depolymerization of glycosaminoglycans comprising exposing an aqueous solution to electron beam radiation, the solution consisting essentially of: (i) water; (ii) a glycosaminoglycane; and (iii) optionally, an organic compound.

Therefore, by definition, the solution of Claim 11 can include no other essential elements other than water, a glycosaminoglycane, and an organic compound to perform the depolymerization process via electron beam radiation claimed therein. As seen in the Examples section beginning on page 7, the depolymerization process according to the present invention is completed in less than 1 hour. See, for example, Table 1.

In contrast, the process described by Cho et al. requires the inclusion of a photocatalyst as an essential element of the depolymerization process therein. To emphasize this point, Applicants submit herewith a certified English translation of the entire Cho et al. document cited by the Examiner. (See, TAB A.) It is important to note that the Examiner has based this rejection on an English translation of the Cho et al. abstract only and the full disclosure of the Cho et al. reference has never been considered during the prosecution of the present application. As seen throughout the specification and Claim 1, Cho et al. disclose a process for manufacturing low molecular weight polysaccharides in a solution that must include a photocatalyst and will not yield a depolymerized polysaccharide suitable for subsequent use without it,

"The present invention relates to the method of manufacturing low molecular weight polysaccharide [by] adding an optical catalyst like peroxide and the titanium dioxide and disassembling the polysaccharide by irradiating the light . . ." (See, Cho et al. translation, "Purpose of the Invention" at p. 2.)

* * *

"As shown in Fig. 4 . . . it is seen that when the optical catalyst [is] not use[d], the decomposition speed is slow, [and] the production efficiency is low." (See, Cho et al. translation, "Comparative Example 1" at p. 5.)

However, in response to Applicants' argument in the response to the first Office Action that the photocatalyst is a critical element taught in the Cho et al. process and is necessarily excluded from Applicants' claims by virtue of the "consisting essentially of" language in Claim 11, the Examiner responded, "The photocatalyst is not seen to make a difference." (See, final Office Action, page 7.) Applicants assert that the Examiner's argument improperly ignores the direct teaching of the cited document and contravenes patent law.

Similar to the situation in the present Office Action, the examiner in *Ex parte James U. Morrison*, 2004 Pat. App. LEXIS 32 (BPAI 2004) (See, TAB B), disregarded an essential element (lipase inhibitor) included in the chemical composition taught in the cited reference. The Applicant in *Morrison* argued that use of the transitional phrase "consisting essentially of" in the rejected claim, which did not include the recitation of a lipase inhibitor, necessarily excluded this critical element. The Board of Patent Appeals & Interferences agreed and in reversing the examiner stated,

"We agree with Appellant that the instant claims do not read on the composition disclosed by [the cited reference]. By using the term 'consisting essentially of', the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of

the invention." Id. at 32, citing *PPG Indus. Inc. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d 1351, 1353-54 (Fed. Cir. 1998).

* * *

"The question, then, is: what are the basic and novel characteristics of the claimed composition? . . . The basic and novel characteristics of the claimed composition do not include inhibition of lipase enzymes. Thus, the addition of a lipase inhibitor would materially affect the basic and novel characteristics of the claimed composition. The claims do not read on the compositions disclosed by [the cited reference], which all contain a lipase inhibitor. The rejection under 35 U.S.C. §102(b) is reversed." Id.

Similar to *Morrison, supra*, inclusion of the transitional phrase "consisting essentially of" in Claim 11 of the present application necessarily excludes a critical element taught in the process of Cho et al., i.e., a photocatalyst, the inclusion of which, also similar to *Morrison*, would materially affect the basic and novel characteristics of the claimed process.

A further demonstration of the requirement of a photocatalyst in the Cho et al. method can be seen in a comparison of Figures 1 and 4 of the Cho et al. document. Figures 1 and 4 show the reduction in the molecular weight of chitosan as a function of time when treated with ultraviolet (UV) light in a solution that includes chitosan, water, and a photocatalyst (titanium dioxide) (Figure 1), as compared with a solution that includes chitosan, water, and no titanium dioxide photocatalyst and also treated with UV light (Figure 4). As seen in Figure 1, the inclusion of a photocatalyst leads to an approximately 50% reduction in molecular weight of the polysaccharide after about 5 hours, and the depolymerization process is completed after about 70 hours of UV irradiation. In contrast, as seen in Figure 4, the omission of a photocatalyst from the solution results in a much less efficient and significantly slower depolymerization rate: a 50% reduction in MW is achieved after about 10 hours. Moreover, depolymerization never goes beyond about 75% even after 70 hours of UV irradiation.

However, in the present invention, and in contrast to the direct teaching of Cho et al., the process of the present application yields a suitably depolymerized glycosaminoglycane in one hour or less. See examples 1-4 of the present application.

Therefore, based on the disclosure of Cho et al., Applicants assert that it was novel and surprising that the present method could achieve such an efficient, complete, and rapid depolymerization of glycosaminoglycanes without the use of a photocatalyst. In addition, there is no teaching or

suggestion in Cho et al. that depolymerization could be achieved by irradiation without a photocatalyst. The photocatalyst component is disclosed as an essential element by Cho et al., and this essential teaching cannot be ignored by the Examiner for the sake of applying the reference.

From the foregoing it is plain that the invention disclosed in Claims 11 and 13 cannot be anticipated by the Cho et al. reference as a matter of law, and therefore reconsideration and withdrawal of the rejection under 35 U.S.C. §102(b) are respectfully requested.

III. 35 U.S.C. §103(a)

The Examiner has rejected Claims 12, 14, and 16 under 35 U.S.C. §103 as being unpatentable over Cho et al., *supra*. With respect to Cho et al., the Examiner states,

"Cho et al. teach preparation of low molecular weight heparin by exposing an aqueous solution of high molecular weight heparin via [sic] to an electron beam." (See, Office Action, page 6.)

However, as outlined above, the Examiner has misapplied the Cho et al. reference by disregarding the teaching of an essential element, i.e., the inclusion of a photocatalyst that is necessary to drive the reaction to completion and to achieve a molecular weight suitable for the purposes described therein.

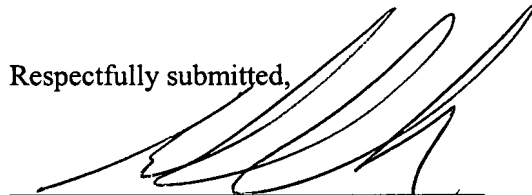
The present invention is directed to a process for the depolymerization of glycosaminoglycans that includes irradiating a solution with an electron beam, the solution consisting essentially of water, a glycosaminoglycane, and optionally an organic compound selected from a well-defined group of compounds. Based on the "consisting essentially of" language of Claim 11 (from which Claims 12, 14, and 16 depend), the above ingredients are the only essential ingredients that may be included in Applicants' process. The process of Cho et al. on the other hand requires an additional essential compound that Applicants' process cannot, namely, a photocatalyst which, as discussed by Cho et al., is critical to the success of their process. By stating that "the photocatalyst is not seen to make a difference", the Examiner is, without stating a reason, impermissibly reading a critical element out of the Cho et al. reference for the purpose of making the rejection. Applicants assert that this is contrary to patent law.

Therefore, as the photocatalyst is a necessary element of the Cho et al. process and, in contrast to the Examiner's assertion, its presence in the process as taught by Cho et al. does make a significant difference, (compare Figs. 1 and 4), Cho et al. can not possibly render obvious a process for efficiently, completely, and rapidly depolymerizing glycosaminoglycans in a solution consisting essentially of

water, a glycosaminoglycane, and optionally an organic compound, which by definition does not include the photocatalyst of Cho et al. For the foregoing reasons, reconsideration and withdrawal of the rejection under 35 U.S.C. §103 are requested

Reconsideration and allowance of Claims 11-16 are respectfully requested.

Respectfully submitted,



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